



UNITED STATES DEPARTMENT OF COMMERCE
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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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08/530,112 07/10/95 MATSUBARA

K 215/070

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| EXAMINER |
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HM12/0307

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| SHUKLA, P | |
| ART UNIT | PAPER NUMBER |

1632
DATE MAILED:

18
03/07/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

08/530,112

Applicant(s)

MATSUBARA ET AL.

Examiner

Ram Shukla

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2000.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,13,21 and 29-68 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,13,21 and 29-68 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

DETAILED ACTION

1. The Examiner prosecuting this application has been changed. Any inquiries relating to the examination of the application should be directed to Examiner Shukla, whereas any inquiries relating to formal matters should be directed to Ms. Pinkney, Patent Analyst. The phone numbers for Examiner Shukla and Patent Analyst Pickney are provided at the end of this office action.
2. Response filed 11-13-00 has been entered.
3. Claims 1, 3, 13, 21, and 29-68 are pending in the instant application.

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 1, 3, 13, 21, and 29-68 remain rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility, for reasons of record set forth in the previous office action of 5-9-2000.

Response to Arguments

Applicant's arguments filed 11-13-00 have been fully considered but they are not persuasive.

Applicants have argued that claimed polynucleotides provide useful probes and primers that can be used for a large variety of biological applications, including for example, gene expression determinations and gene mapping, however, neither the specification nor the Applicants' arguments point out as to the gene whose gene expression, mapping can be determined using the claimed probes and primers? Obviously, in the absence of any knowledge of the function of the protein encoded by the claimed polynucleotides, the probes and primers and gene mapping would be used to carry out further research on the claimed polynucleotide itself, to further define its function, location on the chromosome and expression pattern in a cell or tissue. Same will be true about disease effects, cell or developmental differences, biological function because in the absence of any teachings about the function of the encoded protein, all the argued uses will be to further study the invention itself and characterize it.

Applicants have compared the claimed invention to electrophoretic device, mass spectrometry equipment and other laboratory equipments, however this analogy is not correct since all the argued laboratory equipments are used for analysis of different DNA samples, on the other hand, the probes and primers based on the claimed invention can only be used for further characterizing the claimed polynucleotide itself.

In response, Applicants' citation of case laws, Applicants attention is drawn to *Brenner v. Manson*, 383, US 519 (1966) which states, ".... But a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion. "[A] patent system must be related to the world of commerce rather than to the realm of philosophy. * * *".

Applicants argument that utility requirement does not require particular types of utility is well taken, however, utility requirement does require a specific and substantial asserted utility or a well established utility. Applicants are also referred to Utility Examination Guidelines, Federal Register Vol. 66, No 4, pg. 1092-1099, 201.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1, 3, 13, 21, and 29-68 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for reasons of record set forth in the previous office action of 5-9-00 and 8-16-99.

Response to Arguments

Applicant's arguments filed 11-13-00 have been fully considered but they are not persuasive.

Applicants have argued that ability of the inventors to obtain the unique 3' sequences from the mRNAs, itself demonstrates that the inventors were in possession

of the mRNAs and of fragments of those mRNAs. However, Applicants have ignored the issue Examiner has raised that the specification does not teach the complete structure of any full-length cDNA or gene, nor are any other identifying characteristics disclosed.

Applicants argument, that a unique 3' sequence corresponds to a single mRNA, therefore they identify the corresponding mRNA, cDNA or genomic sequences, are not persuasive because 3' end of a mRNA does not represent the complete sequence structure of the corresponding full length cDNA. It is noted that the specification does not describe what nucleotide sequence will be contained in the full length cDNA, mRNA or genomic sequences or what are other identifying characteristics of the claimed sequences.

8. Claims 1, 3, 13, 21, and 29-68 remain rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above in the rejection under 35 USC § 101 in paragraph 5 and in the office action of 5-9-00, one skilled in the art clearly would not know how to use the claimed invention.

In the event that Applicants might overcome rejection under 35 USC § 101, the 112 first paragraph rejection set forth in the office action of 5-9-00 and 8-16-99 would still apply.

9. Claims 1, 3, 13, 21, and 29-68 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited to polynucleotides consisting of the elected sequences, or fragments thereof, does not reasonably provide enablement for other claims and embodiments for reasons of record set forth in the previous office actions of 5-9-00 and 8-16-99.

Response to Arguments

Applicant's arguments filed 11-13-00 have been fully considered but they are not persuasive. Applicants have indicated that the arguments relating to utility rejection are the same as discussed in the paragraph on utility rejection under 35 USC § 101. Accordingly, applicants are referred to the response in paragraph 5 of this office action. Applicants have further argued that providing the recited sequences is merely routine and does not involve undue experimentation. While it is agreed that isolating the

sequences will not require undue experimentation, it is noted that in the absence of the disclosure in the specification of a specific function for the encoded protein, it would require undue experimentation to use the claimed polynucleotides. An artisan would have to perform extensive experimentation to first establish the function of the protein encoded by the genes due to the lack of the disclosure of the encoded protein in the specification.

10. No claim is allowed.

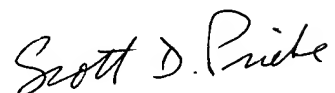
11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Applicants are advised to submit a clean version of each amended claim (without underlining and bracketing) according to § 1.121(c). For instruction, Applicants are referred to <http://www.uspto.gov/web/offices/dcom/olia/aipa/index.htm>.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ram R. Shukla whose telephone number is (703) 305-1677. The examiner can normally be reached on Monday through Friday from 7:30 am to 4:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Karen Hauda, can be reached on (703) 305-6608. The fax phone number for this Group is (703) 308-4242. Any inquiry of a general nature, formal matters or relating to the status of this application or proceeding should be directed to the Kay Pinkney whose telephone number is (703) 305-3553.

Ram R. Shukla, Ph.D.



SCOTT D. PRIEBE, PH.D.
PRIMARY EXAMINER